IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

CAREDX, INC.,	)	
	)	
Plaintiff,	)	
	)	
v.	)	C.A. No. 19-662 (CFC) (CJB)
	)	
NATERA, INC.,	)	**DEMAND FOR JURY TRIAL**
	)	
Defendant.	)	

DEFENDANT NATERA, INC.'S ANSWER, AFFIRMATIVE DEFENSES, AND COUNTERCLAIMS

Defendant Natera, Inc. ("Natera"), by and through its counsel, hereby submits its Answer to Plaintiff CareDx, Inc.'s ("CareDx's") First Amended Complaint (the "FAC"), Affirmative Defenses, and Counterclaims, and demands a trial by jury. Any allegation in the FAC that is not specifically admitted is denied. Natera responds to each of the paragraphs of the FAC as follows:

SUMMARY AND NATURE OF THE ACTION[1]

1. Natera admits that CareDx has contributed to the development of AlloSure. Except as expressly admitted, Natera denies the remaining allegations in Paragraph 1 of the FAC.

[1] Within this Answer, Natera has included headings as they appear in the FAC solely for the sake of the Court's convenience in its review of the pleadings. In doing so, Natera is not admitting to the accuracy or veracity of the headings used in the FAC, and specifically reserves its rights to contest CareDx's characterizations as may be expressed in these headings.

2. Natera admits that CareDx markets and sells AlloSure. Natera is without knowledge or information sufficient to form a belief as to the truth of the remainder of the allegations in Paragraph 2 of the FAC and therefore denies the same.

3. Natera admits that it has obtained trademark protection for "Prospera" and that it has used "Prospera" for its kidney transplant rejection test. Natera admits that researchers at Natera and the University of California, San Francisco co-authored a paper on a new method for using cell-free DNA measurements to assess kidney transplant rejection (the "UCSF Study"). *See* D.I. 1-1. Except as expressly admitted, Natera denies the remaining allegations in Paragraph 3 of the FAC.

4. Natera denies the allegations in Paragraph 4 of the FAC.

5. Natera denies the allegations in Paragraph 5 of the FAC.

6. Natera denies the allegations in Paragraph 6 of the FAC.

7. The allegations in Paragraph 7 of the FAC state legal conclusions for which neither admission nor denial is required. To the extent that an answer is required, Natera denies the allegations and claims for relief in Paragraph 7 of the FAC.

PARTIES

8. Natera admits the allegations in Paragraph 8 of the FAC.

9. Natera is without knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 9 of the FAC and therefore denies the same.

10. Natera admits that CareDx markets and sells AlloSure, which it purports quantifies donor-derived cell-free DNA in transplant recipients. Natera further admits that measuring donor-derived cell-free DNA in a transplant recipient's blood can enable the early detection of kidney transplant rejection. Natera is without knowledge or information sufficient to form a belief as to the truth of the remaining allegations in Paragraph 10 of the FAC and therefore denies the same.

11. Natera admits that it is a corporation organized under the laws of the State of Delaware. Natera admits that its principal place of business is 201 Industrial Road, Suite 410, San Carlos, California, 94070. Natera admits that at the time of the initial Complaint (D.I. 1) it was seeking Medicare coverage determinations for Prospera. Natera admits that it has a CLIA-certified laboratory in San Carlos, California. Except as expressly admitted, Natera denies the remaining allegations in Paragraph 11 of the FAC.

JURISDICTION AND VENUE

12. Natera admits that the FAC alleges claims under the Lanham Act, 15 U.S.C. § 1125(a), et seq. The remaining allegations in Paragraph 12 of the FAC state legal conclusions for which neither admission nor denial is required.

13. The allegations in Paragraph 13 of the FAC state legal conclusions for which neither admission nor denial is required.

14. The allegations in Paragraph 14 of the FAC state legal conclusions for which neither admission nor denial is required.

FACTUAL ALLEGATIONS[2]

15. Natera admits the allegations in the first three sentences of Paragraph 15 of the FAC with respect to the nature of human kidneys. As to the allegations regarding the survival of individuals with end-stage kidney disease in Paragraph 15 of the FAC, Natera is without knowledge or information sufficient to form a belief as to the truth of those allegations and therefore denies the same.

16. Natera admits the allegations in Paragraph 16 of the FAC.

17. Natera admits one method for diagnosis of active rejection ("AR") of a transplanted kidney is assessment, by light microscopy examination, of kidney

[2] To the extent that any subheadings in the "FACTUAL ALLEGATIONS" section of the FAC make allegations requiring a response, Natera denies all such allegations and claims for relief.

tissue obtained from a needle biopsy. Natera admits the allegations in the second sentence of Paragraph 17 of the FAC.

18. Natera admits that a current method of care is based on serial measurements of serum creatinine. Natera is without knowledge or information sufficient to form a belief as to the truth of the remaining allegations in Paragraph 18 of the FAC and therefore denies the same.

19. Natera admits that cell-free DNA are fragments of DNA found in the bloodstream of a transplant recipient. Natera admits that donor-derived cell-free DNA is released from an organ's cells when a transplant recipient's immune system is rejecting a donor kidney. Natera further admits that high levels of donor-derived cell-free DNA in a recipient's blood is an indication that the transplanted organ is being rejected. Natera is without knowledge or information sufficient to form a belief as to the truth of the remaining allegations in Paragraph 19 of the FAC and therefore denies the same.

20. Natera admits that CareDx markets and sells AlloSure. Natera is without knowledge or information sufficient to form a belief as to the truth of the remaining allegations in Paragraph 20 of the FAC and therefore denies the same.

21. Natera admits that CareDx purports to have conducted a clinical trial for AlloSure named Circulating Donor-Derived Cell-Free DNA in Blood for Diagnosing Acute Rejection in Kidney Transplant Recipients. Natera further

admits that a report was published in the *Journal of American Society of Nephrology* in July 2017 (the "Bloom Study"). *See* D.I. 1-2. Natera is without knowledge or information sufficient to form a belief as to the truth of the remaining allegations in Paragraph 21 of the FAC and therefore denies the same.

22. Natera admits the allegation in Paragraph 22 of the FAC.

23. Natera admits that Sensitivity is the measure of the percentage of true positive test results out of all affected cases, including true positive and false negative test results. Natera denies the remaining allegations in Paragraph 23 of the FAC.

24. Natera admits that Specificity is the measure of the percentage of true negative test results out of all affected cases, including true negative and false positive test results. Natera denies the remaining allegations in Paragraph 24 of the FAC.

25. Natera admits the allegations in Paragraph 25 of the FAC.

26. Natera is without knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 26 of the FAC and therefore denies the same.

27. Natera admits that it developed its own cell-free DNA test and that it has used "Prospera" for its kidney transplant rejection test. Natera admits that researchers at Natera contributed to an investigation on a new method of

measuring cell-free DNA to assess kidney transplant rejection. Except as expressly admitted, Natera denies the remaining allegations in Paragraph 27 of the FAC.

28. Natera admits that on December 23, 2018, researchers at Natera and the University of California, San Francisco jointly published the aforementioned UCSF Study in the *Journal of Clinical Medicine*. *See* D.I. 1-1. Except as expressly admitted, Natera denies the remaining allegations in Paragraph 28 of the FAC.

29. Natera admits that the UCSF Study was "a retrospective analysis of blood samples from kidney transplant recipients who had transplant surgeries at the [UCSF] Medical Center." D.I. 1-1 at 2. Natera further admits that in the UCSF Study, "[a]ll kidney biopsies were analyzed in a blinded manner by a UCSF pathologist[.]" *Id.* at 3. As to the allegations regarding the Bloom Study in Paragraph 29 of the FAC, Natera is without knowledge or information sufficient to form a belief as to the truth of those allegations and therefore denies the same. Except as expressly admitted, Natera denies the remaining allegations in Paragraph 29 of the FAC.

30. Natera admits that "[o]f the 178 unique patients included in the [UCSF] study, 20% (35) were under 18 years of age[.]" D.I. 1-1 at 4. Natera further admits that in the UCSF Study, patients who are under 18 years of age are classified as "Stable," "Borderline [Active Rejection]," "Other Injury," or "Combined." *See id.* at 5 (Table 1). As to the allegations regarding the Bloom

Study in Paragraph 30 of the FAC, Natera is without knowledge or information sufficient to form a belief as to the truth of those allegations and therefore denies the same. Except as expressly admitted, Natera denies the remaining allegations in Paragraph 30 of the FAC.

31. Natera admits that according to the UCSF Study, "[a] total of 300 plasma samples were collected from 193 unique renal transplant recipients." D.I. 1-1 at 4. Natera admits that in the UCSF Study, "23 samples from 15 patients did not meet inclusion criteria and were excluded from analyses; this included samples collected within three days from transplant (15), and samples unable to be sequenced (8)." *Id.* Natera further admits that "[o]f the remaining 277 samples, 217 were biopsy-matched[.]" *Id.* Natera admits that a presentation from an investor call dated June 27, 2018, nearly six months before the publication of the UCSF Study, is attached to its Form 8-K filing with the Securities and Exchange Commission. *See* D.I. 1-3. Natera further admits that the presentation contains a slide, which states that "292 samples from 187 patients were analyzed." *Id.* at 7. Except as expressly admitted, Natera denies the remaining allegations in Paragraph 31 of the FAC.

32. Natera admits that "for cause" kidney biopsies are conducted on patients for whom a warning sign about active rejection ("AR") has been triggered. Natera admits that a "protocol" biopsy is conducted on patients who have no prior

indication of AR. Natera further admits that "[a]mong the biopsy-matched samples [in the UCSF Study], 103 (47.5%) were biopsied for clinical reasons [or for-cause], whereas 114 (52.5%) were biopsied according to protocol." D.I. 1-1 at 9; *see also id.* (Table 3). Except as expressly admitted, Natera denies the remaining allegations in Paragraph 32 of the FAC.

33. Natera admits that the UCSF Study delineates the number of "for-cause" and "protocol" biopsies for each of the following groups: AR, borderline ("BL"), other injury ("OI"), and stable ("STA"). *See* D.I. 1-1 at 9 (Table 3). Except as expressly admitted, Natera denies the remaining allegations in Paragraph 33 of the FAC.

34. Natera admits that the Banff Classification of Allograft Pathology ("the Banff Rules") is a classification for the reporting of biopsies from solid organ transplants. Natera admits that the Banff Rules provide criteria for the diagnosis of types of kidney rejections. Natera is without knowledge or information sufficient to form a belief as to the truth of the remaining allegations in Paragraph 34 of the FAC and therefore denies the same.

35. Natera admits that the parenthetically quoted language in the first sentence of Paragraph 35 of the FAC is in the publication from the UCSF Study. *See* D.I. 1-1 at 5. Natera admits that according to the UCSF Study, "[i]n this data set, the performance of the assay to detect rejection was elevated for all types of

rejection combined (ABMR, TCMR)." *Id.* As to the allegations regarding the Bloom Study in Paragraph 35 of the FAC, Natera is without knowledge or information sufficient to form a belief as to the truth of those allegations and therefore denies the same. Except as expressly admitted, Natera denies the remaining allegations in Paragraph 35 of the FAC.

36. Natera denies the allegations in Paragraph 36 of the FAC.

37. Natera denies the allegations in Paragraph 37 of the FAC.

38. The allegations in Paragraph 38 of the FAC state legal conclusions for which neither admission nor denial is required. To the extent that an answer is required, Natera denies the allegations and claims for relief in Paragraph 38 of the FAC.

39. Natera denies the allegations in Paragraph 39 of the FAC.

40. Natera admits that a Natera press release dated June 21, 2018, more than six months before the publication of the UCSF Study, states "[t]his performance data suggests the potential of Natera's assay for use in both rule-in and rule-out applications" and "[t]his sensitivity compares favorably against competition, which reported only 59% sensitivity in a 2017 study." *See* D.I. 1-4 at 1. Natera admits that the June 21, 2018 press release states "[i]n a blinded, retrospective study, Natera leveraged its validated SNP (Single Nucleotide Polymorphism) technology to measure donor-derived cell-free DNA levels (dd-

cfDNA) in 300 plasma samples from 193 unique kidney transplant patients, including 52 patients experiencing acute rejection." *Id.* Except as expressly admitted, Natera denies the remaining allegations in Paragraph 40 of the FAC.

41. Natera admits that its June 27, 2018 Form 8-K filing with the Securities and Exchange Commission contains a presentation from an investor call dated June 27, 2018, nearly six months before the publication of the UCSF Study. *See* D.I. 1-3. Natera admits that a slide in the presentation from the June 27, 2018 investor call states "Natera Assay Outperforms Competition." *Id.* at 10. Natera further admits that this slide in the presentation from the June 27, 2018 investor call includes a table with two columns: one for "Natera study (n= 292 samples)" and the other for "Bloom et al. (n= 107 samples)," and states "specificity" under "Natera study" of "73% (n=240)" and states "specificity" under "Bloom et al." of "85% (n=80)." *Id.* Except as expressly admitted, Natera denies the remaining allegations in Paragraph 41 of the FAC.

42. Natera admits that its Prospectus Supplement dated July 12, 2018, more than five months before the publication of the UCSF Study, states "[i]n a blinded, retrospective study, Natera leveraged its validated SNP (Single Nucleotide Polymorphism) technology to measure donor-derived cell-free DNA levels (dd-cfDNA) in 292 plasma samples from 187 unique kidney transplant patients, including 52 patients experiencing acute rejection." *See* D.I. 1-5 at 13. The

Prospectus Supplement dated July 12, 2018 states: "Natera's dd-cfDNA assay demonstrated 92% sensitivity in detecting acute rejection, identifying 48 out of 52 affected cases based on a cutoff of 1% dd-cfDNA. This sensitivity compares favorably against competition, which reported only 59% sensitivity in a 2017 study." *Id*. Except as expressly admitted, Natera denies the remaining allegations in Paragraph 42 of the FAC.

43. Natera admits that its January 7, 2019 press release states the following: "Natera, Inc…, a leader in cell-free DNA, today announced clinical validation study results published in the *Journal of Clinical Medicine*, demonstrating the highly accurate performance of its donor-derived cell-free DNA (dd-cfDNA) test for active allograft rejection in kidney transplant recipients, including higher sensitivity and nearly 18% higher area under the curve (AUC) than the competitive dd-cfDNA assay." D.I. 1-6 at 1. The January 7, 2019 press release states "[t]he study results also showed higher sensitivity (89% vs. 59%) and higher AUC (0.87 vs. 0.74) than the competitive dd-cfDNA assay." *Id*. at 2. Except as expressly admitted, Natera denies the remaining allegations in Paragraph 43 of the FAC.

44. Natera admits that its "Natera Company Presentation / J.P. Morgan Healthcare Conference" dated January 9, 2019, states: "[h]ighest area under the curve; driven by superior clinical data," and "[f]irst test to consistently detect

subclinical acute rejection (20-25% of cases)." D.I. 1-7 at 1, 12. Except as expressly admitted, Natera denies the remaining allegations in Paragraph 44 of the FAC.

45. Natera admits that at the 2019 J.P. Morgan Healthcare Conference, Steve Chapman, President and CEO of Natera, gave an oral presentation. As to the words attributed to President Chapman in Paragraph 45 of the FAC, the FAC contains insufficient information to permit Natera to form a belief as to the truth or falsity of those allegations and therefore Natera denies the same. Except as expressly admitted, Natera denies the remaining allegations in Paragraph 45 of the FAC.

46. Natera admits that its February 1, 2019 press release states: "In a recent study published in the *Journal of Clinical Medicine*, Natera's assay detected acute rejection (AR) with 89% sensitivity and 0.87 area under the curve (AUC). This test performance compares favorably to the current standard of care, which is based on serial measurements of serum creatinine; and it compares favorably against competition, which in a 2017 study reported 59% sensitivity and 0.74 AUC." D.I. 1-8 at 3. The February 1, 2019 press release states: "No other dd-cfDNA assay has been shown to detect TCMR or validated to detect subclinical AR, which occurs in 20-25% of patients in the first two years post-transplant, and

which is considered a major driver of graft failure." *Id*. Except as expressly admitted, Natera denies the remaining allegations in Paragraph 46 of the FAC.

47. Natera admits that the statements "The excellent analytical performance of Natera's dd-cfDNA assay underpins its superior clinical performance in detecting active allograft rejection (AR)" and "In its recently published clinical validation study, Natera reported higher sensitivity (89% vs. 59%) and higher area under the curve (0.87 vs. 0.74) than the competing dd-cfDNA assay" are from a Natera press release dated February 22, 2019. *See* D.I. 1-9 at 2. Except as expressly admitted, Natera denies the remaining allegations in Paragraph 47 of the FAC.

48. Natera admits that the statement "Natera's assay detected acute rejection (AR) with 89% sensitivity and 0.87 area under the curve (AUC). This test performance . . . compares favorably against competition, which in a 2017 study reported 59% sensitivity and 0.74 AUC" is from an undated document further stating: "Natera Announces Agreement with One Lambda to Co-Distribute Its Kidney Transplant Rejection Test." *See* D.I. 1-10. As to the inclusion of this document in a conference bag, the FAC contains insufficient information to permit Natera to form a belief as to the truth or falsity of those allegations and therefore Natera denies the same. Except as expressly admitted, Natera denies the remaining allegations in Paragraph 48 of the FAC.

49. Natera admits that the statement "Natera reported higher sensitivity (89% vs. 59%) and higher area under the curve (0.87 vs. 0.74) than the competing ddcfDNA assay" is from a Natera press release dated March 29, 2019. *See* D.I. 1-11 at 2. Except as expressly admitted, Natera denies the remaining allegations in Paragraph 49 of the FAC.

50. Natera denies the allegations in Paragraph 50 of the FAC.

51. Natera admits that as a genetic testing and diagnostics company, it develops and commercializes non-invasive methods for analyzing DNA. Except as expressly admitted, Natera denies the remaining allegations in Paragraph 51 of the FAC.

52. Natera denies the allegations in Paragraph 52 of the FAC.

53. Natera denies the allegations in Paragraph 53 of the FAC.

CAUSES OF ACTION

COUNT ONE – LANHAM ACT VIOLATION
(False Advertising in Violation of 15 U.S.C. § 1125(a))

54. Natera incorporates its answers to the allegations contained in Paragraphs 1-53 of the FAC as if set forth fully herein.

55. Natera denies the allegations in Paragraph 55 of the FAC.

56. Natera denies the allegations in Paragraph 56 of the FAC.

57. Natera denies the allegations in Paragraph 57 of the FAC.

58. Natera denies the allegations in Paragraph 58 of the FAC.

59. Natera denies the allegations in Paragraph 59 of the FAC.

60. The allegations in Paragraph 60 of the FAC state legal conclusions for which neither admission nor denial is required. To the extent that an answer is required, Natera denies the allegations in Paragraph 60 of the FAC.

COUNT TWO
(Common Law Unfair Competition)

61. Natera incorporates its answers to the allegations contained in Paragraphs 1-60 of the FAC as if set forth fully herein.

62. Natera denies the allegations in Paragraph 62 of the FAC.

63. Natera denies the allegations in Paragraph 63 of the FAC.

64. Natera denies the allegations in Paragraph 64 of the FAC.

65. Natera denies the allegations in Paragraph 65 of the FAC.

66. The allegations in Paragraph 66 of the FAC state legal conclusions for which neither admission nor denial is required. To the extent that an answer is required, Natera denies the allegations in Paragraph 66 of the FAC.

COUNT THREE
(Delaware Uniform Deceptive Trade Practices Act, 6 Del. C. §§ 2532(a)(5), (8), (12))

67. Natera incorporates its answers to the allegations contained in Paragraphs 1-66 of the FAC as if set forth fully herein.

68. The allegations in Paragraph 68 of the FAC state legal conclusions for which neither admission nor denial is required. To the extent that an answer is required, Natera denies the allegations in Paragraph 68 of the FAC.

69. Natera denies the allegations in Paragraph 69 of the FAC.

70. Natera denies the allegations in Paragraph 70 of the FAC.

71. Natera denies the allegations in Paragraph 71 of the FAC.

72. Natera denies the allegations in Paragraph 72 of the FAC.

73. The allegations in Paragraph 73 of the FAC state legal conclusions for which neither admission nor denial is required. To the extent that an answer is required, Natera denies the allegations in Paragraph 73 of the FAC.

74. Natera denies all allegations of the FAC not specifically admitted above.

DEFENSES AND AFFIRMATIVE DEFENSES

Natera hereby sets forth defenses to CareDx's FAC. Natera sets forth the following matters to apprise CareDx of certain applicable defenses. By listing any matter as a defense herein, Natera does not assume the burden of proving any matter upon which CareDx, or any other party, bears the burden of proof under applicable law.

FIRST AFFIRMATIVE DEFENSE

The FAC, in whole or in part, fails to state a claim against Natera upon which relief can be granted.

SECOND AFFIRMATIVE DEFENSE

The FAC may be barred, in whole or in part, because CareDx lacks standing to bring its claims pursuant to the Lanham Act, 15 U.S.C. § 1125(a).

THIRD AFFIRMATIVE DEFENSE

The FAC may be barred, in whole or in part, because the statements alleged therein concern matters of which there is legitimate ongoing scientific disagreement and are therefore not actionable.

FOURTH AFFIRMATIVE DEFENSE

The FAC may be barred, in whole or in part, by the doctrine of unclean hands.

FIFTH AFFIRMATIVE DEFENSE

The FAC may be barred, in whole or in part, by the doctrine of estoppel.

SIXTH AFFIRMATIVE DEFENSE

The FAC may be barred, in whole or in part, because CareDx cannot show that it will suffer irreparable harm.

SEVENTH AFFIRMATIVE DEFENSE

The FAC may be barred, in whole or in part, because CareDx has suffered no injury or damages.

EIGHTH AFFIRMATIVE DEFENSE

The FAC may be barred, in whole or in part, because CareDx failed to mitigate damages, if such damages exist.

NINTH AFFIRMATIVE DEFENSE

The FAC may be barred, in whole or in part, because, to the extent CareDx has suffered any alleged injury or damages, which Natera denies, such injury or damages were not caused, proximately or otherwise, by any action of Natera.

TENTH AFFIRMATIVE DEFENSE

The FAC may be barred, in whole or in part, because CareDx's alleged injuries and damages, if any, were caused, including proximately caused, by the actions, inactions, and/or omissions of other persons, firms, corporation, governmental bodies, or entities for which Natera is not responsible.

ELEVENTH AFFIRMATIVE DEFENSE

The FAC may be barred, in whole or in part, because CareDx's alleged injuries and damages, if any, were caused, including proximately caused, by the actions, inactions, and/or omissions of CareDx.

TWELFTH AFFIRMATIVE DEFENSE

The FAC may be barred, in whole or in part, because the acts, conduct, and/or omissions alleged arise from a reasonable exercise of business judgment.

THIRTEENTH AFFIRMATIVE DEFENSE

The FAC may be barred, in whole or in part, because CareDx has an adequate remedy at law for any claims to equitable or injunctive relief.

FOURTEENTH AFFIRMATIVE DEFENSE

The FAC may be barred, in whole or in part, because the speech complained of by CareDx is protected under the First Amendment. *See, e.g.*, *44 Liquormart, Inc. v. Rhode Island*, 517 U.S. 484 (1996); *Rubin v. Coors Brewing Co.*, 514 U.S. 476 (1995).

FIFTEENTH AFFIRMATIVE DEFENSE

The FAC contains insufficient information to permit Natera to raise all appropriate defenses, and therefore, Natera reserves the right to amend and/or supplement these defenses and to assert additional defenses.

ADDITIONAL DEFENSES AND AFFIRMATIVE DEFENSES

Additional defenses may be disclosed by discovery or additional factual allegations made by CareDx. Accordingly, Natera reserves the right to amend, modify, revise, or supplement its Answer, or to plead such further defense and/or

take such further actions that may be necessary and proper to preserve such additional defenses.

WHEREFORE, Natera requests that this Court: (1) find in Natera's favor, and against CareDx, on each of the claims raised in the FAC; (2) award Natera its attorneys' fees and costs for this action as provided by law; and (3) award Natera any such further relief as the Court may deem just and proper.

NATERA'S COUNTERCLAIMS AGAINST CAREDX

In support of its Counterclaims against CareDx, Natera alleges as follows:

NATURE OF THE ACTION

1. In response to the allegations made by CareDx in the First Amended Complaint, Natera seeks a declaratory judgment that it has not engaged in false advertising, unfair competition, or violations of the Delaware Uniform Deceptive Trade Practices Act.

2. Additionally, Natera seeks monetary and injunctive relief for CareDx's false advertising, tortious interference with Natera's prospective economic advantage, CareDx's unfair competition, and CareDx's violations of the Delaware Uniform Deceptive Trade Practices Act.

3. As set forth below, CareDx has embarked on a malicious campaign to deceive physicians and healthcare providers by discouraging interest in Natera's cfDNA kidney transplant diagnostic test (Prospera®), improperly attempting to

shield CareDx from competition, and putting patients at risk. CareDx's campaign has included false and misleading advertising and promotion, improper public statements by its employees and agents and, on information and belief, improper statements by its employees and agents in private settings with healthcare providers, as well as meritless litigation. Contrary to law, these actions and statements have been made with the intent to unfairly disparage Natera's Prospera® product, to discourage fair and legal competition in the marketplace by Natera, and to benefit CareDx's present and future sales of its own product (AlloSure®).

JURISDICTION AND VENUE

4. The Court has subject matter jurisdiction over Natera's declaratory judgment counterclaims pursuant to 28 U.S.C. §§ 2201 & 2202. The Court has supplemental jurisdiction over Natera's state law counterclaims pursuant to 28 U.S.C. § 1367(a) because they are related both to Natera's counterclaims and to the affirmative claims advanced by CareDx in the First Amended Complaint.

5. The Court has personal jurisdiction over CareDx because CareDx is a Delaware corporation and has consented to jurisdiction in this District by filing this action.

6. Venue is proper in this Court pursuant to 28 U.S.C. § 1391(b)(2) because CareDx is a Delaware corporation and has consented to this venue by filing this action.

FACTUAL ALLEGATIONS

7. On December 23, 2018, researchers at Natera and the University of California, San Francisco jointly published a study in the *Journal of Clinical Medicine* discussing a new method developed by Natera for using cell-free DNA ("cfDNA") measurements to assess kidney transplant rejection ("the UCSF Study"). *See* D.I. 1-1. The UCSF Study analyzed a total of 217 samples from patients who had undergone kidney transplants at UCSF Medical Center and involved the work of 19 researchers over the course of more than a year.

8. The UCSF Study addressed Natera's new methods for measuring cfDNA levels and interpreting those measurements to identify kidney transplant rejection and injury. Since publication, the findings of the UCSF Study have been cited multiple times by others working in the field, reflecting the scientific value and utility of the UCSF Study.

9. The UCSF Study presented the results of the largest biopsy-matched study conducted in renal transplantation assessing the use of cell-free DNA. It was also the first to publish performance of cell-free DNA testing in a subclinical, surveillance setting.

10. In addition, the UCSF Study was the first to clinically validate a cfDNA-based transplant rejection test to identify both T-cell mediated rejection and antibody mediated rejection.

11. Since the publication of the UCSF Study, another peer-reviewed publication further demonstrated the utility of Natera's test, confirming that the test can assess the risk of active renal allograft rejection with greater precision than other biomarkers or other donor-derived cfDNA ("dd-cfDNA") tests on the market.[3]

12. Since the publication of the UCSF Study, Natera has continued to investigate and pursue steps to commercialize the test it developed using its new methods. In 2019, Natera launched Prospera®, the commercial name for its kidney transplant diagnostic test. Natera also announced ProActive, a prospective registry study for kidney transplant recipients using Prospera®, which will follow approximately 3,000 renal transplant patients over three years.

13. On December 19, 2019, Natera announced it had obtained final Medicare coverage for Prospera®. This coverage was awarded despite CareDx's efforts to interfere in the review process with meritless attempts to undermine the evidence before the Molecular Diagnostic Services (MolDX®) Program, which establishes coverage and reimbursement for molecular diagnostic tests and completes technical assessments of published test data in connection with coverage administered by the Centers for Medicare and Medicaid Services. During the

[3] *See* Ex. 1 (Altug Y, Liang N, Ram R, et al. Analytical validation of a single-nucleotide polymorphism-based donor-derived cell-free DNA assay for detecting rejection in kidney transplant patients. *Transplantation*. 2019;103: 2657-2665).

MolDX review process, members of the public were permitted to submit comments. Natera received 11 positive comments, and 3 negative comments.[4] On information and belief, all three negative comments are associated with CareDx. One of the negative comments was CareDx's own baseless submission criticizing Prospera®. On information and belief, the other two negative comments were from paid advisors to CareDx. CareDx's efforts to interfere failed. Natera was awarded coverage. In fact, according to the relevant Local Coverage Determinations (LCDs) issued by MolDX, Natera's "Strength of [E]vidence" to warrant Medicare coverage is higher than that of CareDx.[5]

14. Beyond its attempts to interfere with Natera's obtaining Medicare coverage, CareDx also has unlawfully interfered with Natera's efforts to translate its extensive investment in research and resulting innovative technology into a kidney transplant diagnostic test for patients. By way of example, CareDx has falsely and misleadingly represented to healthcare providers and others in the industry that: (a) Natera's clinical data is not accurate—although it is and was independently ranked higher in strength than CareDx's by MolDX; (b) Natera's assay in no way compares favorably to CareDx's corresponding assay—although it

[4] *See* Ex. 2 (*Local Coverage Article: Response to Comments: MolDX: Prospera (A57821)*, Ctrs. for Medicare & Medicaid Servs. (Dec. 19, 2019)).

[5] *Compare* Ex. 3 at 7 (stating that Prospera's "Strength of [E]vidence" is "Moderate") *with* Ex. 4 at 7 (stating that AlloSure's "Strength of [E]vidence" is "Limited").

does; (c) Natera's research and the scientists who have carried it out cannot be trusted—although they can be; (d) CareDx's assay is the "only" cfDNA kidney transplant diagnostic—though it isn't; and (e) CareDx's assay performs as well as its marketing materials suggest—though it doesn't.

15. In addition to CareDx's meritless and fruitless attempts to influence the MolDX evaluation of Prospera®, on information and belief, in industry conferences and through industry publications, CareDx and its agents represented to healthcare providers, industry participants, and potential customers that the data in the UCSF Study is not accurate, cannot be compared favorably with CareDx's publication of its assay (the "Bloom Study") (*see* D.I. 1-2), and that it cannot be trusted—all of which are false. Again, the natural effect of these false and misleading representations is the incorrect impression that Prospera® is inferior to CareDx's AlloSure product.

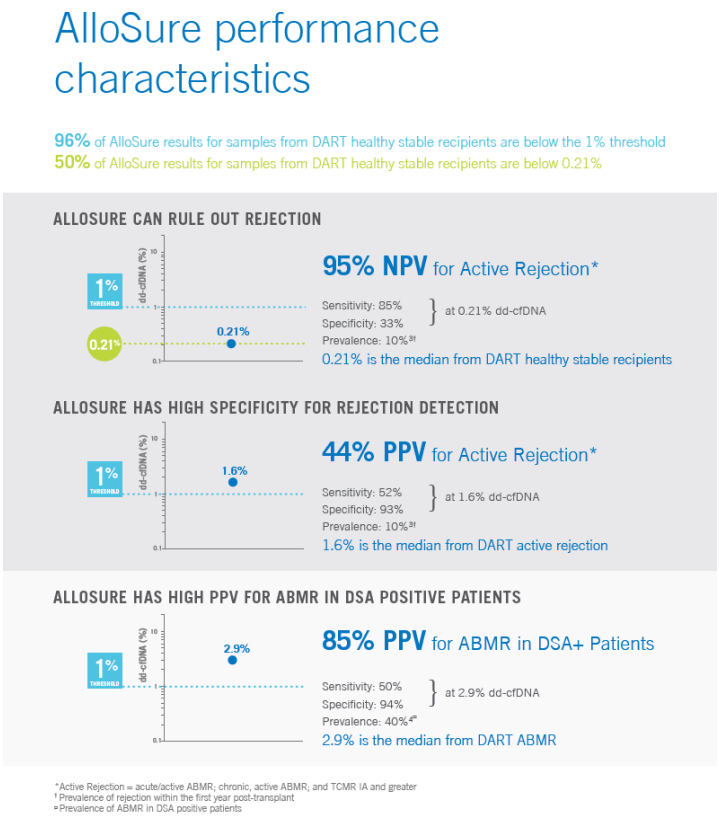
16. On April 10, 2019, CareDx also published a false and misleading press release in which it falsely and improperly accused Natera of deliberately misleading consumers. In that press release, CareDx claimed that Natera's statements regarding the UCSF Study constituted "a concerted effort by Natera to mislead patients and medical personnel into thinking its study was more credible than it actually was and that it proved Natera's technology is superior to CareDx's,

which it is not."[6] That is false. On information and belief, the press release containing this statement was intended to unlawfully discourage others from expressing interest in Prospera®.

17. CareDx also has unlawfully interfered with Natera's efforts to provide a kidney transplant diagnostic test to patients by falsely and misleadingly representing the performance of its own kidney transplant diagnostic test, AlloSure. By way of example, in or around March 2018, in a brochure advertising AlloSure excerpted below, CareDx falsely and misleadingly represented the positive predictive value (PPV) and negative predictive value (NPV) of its test.[7] PPV is a measure of how likely a positive test result actually describes a transplant rejection, while NPV is a measure of how likely a negative test result actually describes a transplant recipient not experiencing rejection. PPV and NPV are important measures of test performance and may have significant influence on which tests physicians choose to order for their patients. PPV and NPV values may suggest to the physician how reliable or robust the test results will be. Misrepresenting AlloSure's PPV and NPV serves to deceive physicians and healthcare providers, and can have an adverse impact on patient care and patient outcomes by misstating the extent to which physicians can truly rely upon the test.

[6] Ex. 5 at 1 (CareDx's April 10, 2019 Press Release).

[7] Ex. 6 at 6 (CareDx's March 2018 AlloSure Brochure).



18. CareDx's brochure is a classic example of "bait and switch" marketing. CareDx isolates particular slices of data, manipulating categories and cutoffs to generate numbers that look favorable. Not only that, CareDx's brochure creates the false impression that such reporting of data from disparate cohorts, or the same cohort with two different classification thresholds applied simultaneously, are somehow representative of a physician's likely clinical experience.

19. For example, CareDx uses one threshold to claim a high NPV, omits the correspondingly low PPV, and then uses a ***different threshold in the same patient cohort*** to inflate the reported PPV. Specifically, the CareDx brochure

shows information about PPV and NPV calculated for the same clinical cohort with a rejection prevalence of 10%. CareDx claims a PPV of 44% and an NPV of 95% on the same figure, with a classification threshold indicated on the figure at 1%. The target audience would understand this to mean that AlloSure provides a PPV of 44% and an NPV of 95% in this clinical cohort, using the classification threshold at 1%—the same threshold discussed in CareDx's validation publications and Medicare filings. But these PPV and NPV values are not and could not be achieved using a 1% threshold. Rather, CareDx extrapolates them by using two different classification thresholds (1.6% and 0.21%) which cannot be applied simultaneously to the same patient in the same test. Indeed, the use of the 0.21% classification threshold results in significantly lower PPV—a fact left conspicuously unstated in the brochure. Such mixing of thresholds could not and would not ever occur within a single patient or cohort.

20. The same brochure graphic also indicates 85% PPV for ABMR in DSA+ patients, again with the 1% classification threshold indicated on the figure. However, in order to actually get to a 85% PPV, CareDx must use a 2.9% dd-cfDNA classification threshold. This much higher threshold results in a significantly lower NPV in this higher-prevalence clinical population, but again, that lower NPV does not appear in the brochure. Instead, only the 95% NPV—calculated from a different threshold ***and*** a different population, appears in the

brochure. Because the actual (and much lower) NPV experienced by patients from a DSA+ population classified with a 2.9% threshold is not displayed, the reader is misled into assuming that the 95% NPV still applies even though the real performance must be significantly worse.

21. CareDx's target audience would be unlikely to sort out these marketing claims and correct their expectations based on the limitations described above. More likely, physicians mistakenly believe that the test offered by CareDx has a PPV of 85% and an NPV of 95%. In clinical practice, this means that physicians are not only likely to miss active rejection for a patient under suspicion of rejection but also order an inappropriate and unnecessary invasive biopsy in a surveillance setting. CareDx's misleading marketing puts patients at risk. By presenting a false and misleading representation of AlloSure's performance, CareDx further implies that AlloSure's performance is better than it is, and that it is comparable to, or more effective than Natera's Prospera® product.

22. CareDx has further misrepresented the quality of AlloSure as a useful tool for detection of rejection in transplant recipients.[8] With a threshold of 1.0%, AlloSure has 59% sensitivity.[9] As a consequence, AlloSure misses 41% of rejections. A key reason behind this is that AlloSure is not able to detect T-cell

[8] *Id.* at 10.

[9] D.I. 1-2 at 2223 ("With a cutoff of 1.0%, dd-cfDNA had an 85% specificity … and 59% sensitivity ... to discriminate active rejection from no rejection.").

mediated rejection ("TCMR"), which comprises nearly a third of all rejections in the United States.[10] An independent peer-reviewed manuscript published in 2019 confirms CareDx's inability to detect TCMR. The paper states that "We found that dd-cfDNA was not able to discriminate [T]CMR from no rejection."[11]

23. Despite these shortcomings, CareDx misleadingly suggests that the latest incarnation of its test, AlloSure 3.0, is suitable for a new use in a surveillance context and provides clinical information about TCMR in that context. For example, in a recent comment to the press on AlloSure 3.0, CareDx noted that it "can now stratify patients with t-cell mediated rejection"—in other words, assign a risk status to a patient and use that information to make treatment decisions in connection with TCMR.[12] But physicians using the test at Cedars-Sinai Medical Center have already reported that "dd-cfDNA was not able to discriminate [T]CMR from no rejection."[13]

24. A CareDx promotional communication further conflates the difference between use in detecting TCMR—which AlloSure cannot do—and the

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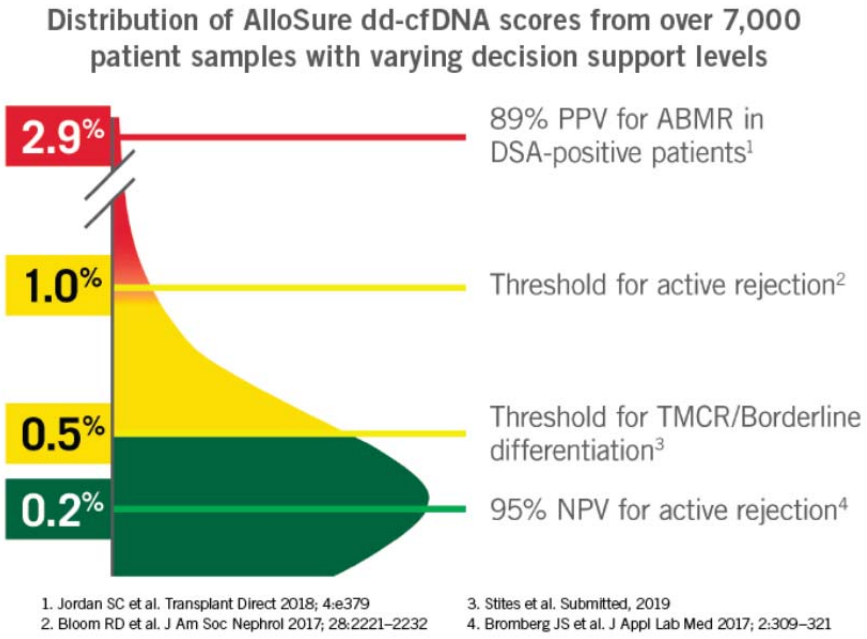
[10] Ex. 7 at 1664 (Huang, et al. Early clinical experience using donor-derived cell-free DNA to detect rejection in kidney transplant recipients. Transplantation. 2019, doi: 10.1111/ajt. 15289).

[11] *Id*. at 1666.

[12] Ex. 8 at 1 (*CareDx, Inc. (CDNA) Update from the 31st Annual PJ Healthcare Conference*, Piper Jaffray (Dec. 4, 2019)).

[13] Ex. 7 at 1666.

very different use to "risk-stratify" patients already known to have TCMR.[14] CareDx misleadingly conflates in the same diagram the 1% threshold for detection, and the 0.5% threshold for risk-stratification.



The effect of this misleading promotion is to suggest to customers that AlloSure can provide detection of TMCR in a surveillance context, which is false. And by this misleading representation of AlloSure's performance, CareDx further implies that AlloSure's performance is better than it is, and that it is comparable to, or more effective than Natera's Prospera® product.

25. CareDx's marketing brochures also contain other statements that are both false and misleading. For example, in a recent brochure circulated by CareDx

[14] Ex. 9 at 2 (*AJT Accepts Publication, AlloSure Differentiates Ambiguous Rejection*, CareDx, available at https://mailchi.mp/caredx.com/tcmr1a?e=5708afee96 (last visited Feb. 5, 2020)).

at the American Society of Transplant Surgeons ("ASTS") Symposium in Miami, Florida, CareDx makes the following false and misleading statements:

- "AlloSure Kidney: The ***only*** transplant specific cfDNA test."[15] This statement is false because Prospera® is also on the market, tests cfDNA using Natera's proven platform, and is specifically designed for kidney transplant recipients.
- Misleadingly reports NPV and PPV values from two different contexts—a "95% NPV" for "active rejection" in "healthy stable recipients" and an "89% PPV" for "AMBR in DSA+ Patients."[16] These representations are false and misleading for at least the reasons discussed above at Paragraphs 17-21.
- Though AlloSure is not validated for surveillance settings, CareDx markets it as a "surveillance test."[17]

26. On or about July 16, 2019, Seeking Alpha published an "Editor's Pick" article describing how CareDx's kidney transplant diagnostic test, AlloSure, had failed to perform as CareDx had represented. The article stated, among other points: "Recent clinical studies confirm that AlloSure … is ineffective in

[15] Ex. 10 at 1(CareDx's Brochure from ASTS Symposium) (emphasis added); *see also id.* at 3-4.

[16] *Id.* at 10.

[17] Ex. 6 at 10.

diagnosing kidney rejection, and dangerous if used as directed by the company."[18] It further reported, "Doctors studying and using AlloSure as a screening test are rapidly terminating its use in their patients, resulting in attrition rates of about 25% per quarter."[19]

27. These statements by CareDx and its agents, along with others that Natera expects will be confirmed through discovery, constitute false advertising under the Lanham Act, have tortiously interfered with Natera's prospective economic advantage, constitute unfair competition under Delaware law, and violate Delaware's prohibition on unfair and deceptive trade practices.

CAUSES OF ACTION

COUNT ONE
DECLARATORY JUDGMENT OF NO FALSE ADVERTISING

28. Natera incorporates by reference all allegations set forth above as if fully set forth herein.

29. None of the statements identified by CareDx in connection with this lawsuit are actionable as false advertising under 15 U.S.C. § 1125(a) and Natera seeks a declaratory judgment to that effect.

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[18] Ex. 11 at 1 (*CareDx, Inc.: Poor Prognosis For Key Transplant Rejection Test*, Seeking Alpha (July 16, 2019), available at https://seekingalpha.com/article/4275152-caredx-inc-poor-prognosis-key-transplant-rejection-test).

[19] *Id.*

30. CareDx has not identified any statement by Natera that is "false on its face" or "literally true, but given the merchandising context . . . likely to mislead and confuse consumers." Each of the statements identified by CareDx to date is rooted in valid scientific data and none of the claims made by Natera go beyond that scientific data. Thus, there is no evidence to support the claim that any of Natera's statements are "false" or "likely to mislead and confuse consumers."

31. CareDx has also not identified any statement by Natera that constitutes "actual deception or at least [has] a tendency to deceive a substantial portion of the intended audience." There is no evidence that any statements by Natera have deceived anyone, let alone members of the intended audience. Moreover, the statements complained of by CareDx were made to sophisticated members of the public. Doctors and institutional investors are sophisticated readers who can and do verify the claims that are being made. There is no evidence showing that anyone was deceived by any Natera statement.

32. CareDx has not identified any statement by Natera that could be said to be "material" to a purchasing decision. All of the statements identified by CareDx pre-date the launch of Prospera® by months and there is no evidence that any consumer read these statements and was influenced by them when deciding whether to purchase CareDx's AlloSure product.

33. CareDx has not identified any way in which it has allegedly been injured by the statements. On information and belief, there is no evidence that CareDx has lost sales or goodwill because of Natera's statements.

34. Accordingly, Natera is entitled to a judgment declaring that the statements complained of are not false advertising.

COUNT TWO
DECLARATORY JUDGMENT OF NO UNFAIR COMPETITION

35. Natera incorporates by reference all allegations set forth above as if fully set forth herein.

36. On information and belief, CareDx did not have any reasonable expectancy of entering into a valid business relationship with any consumers in Delaware.

37. Natera has not wrongfully interfered with any valid business relationship of CareDx.

38. CareDx did not have a legitimate expectancy that was defeated by any Natera conduct and CareDx has not suffered any harm due to any Natera conduct.

39. Accordingly, Natera is entitled to a judgment declaring that it has not engaged in unfair competition under Delaware law.

COUNT THREE
DECLARATORY JUDGMENT OF NO VIOLATION OF
THE DELAWARE UNIFORM DECEPTIVE TRADE PRACTICES ACT
6 Del. C. §§ 2532(a)(5), (8), (12)

40. Natera incorporates by reference all allegations set forth above as if fully set forth herein.

41. Natera has not violated subsections 5, 8, or 12 of the Delaware Uniform Deceptive Trade Practices Act (the "DTPA").

42. Natera has not made false and misleading statements representing that Prospera® has uses or benefits that it does not have and has not otherwise violated Section 5 of the DTPA.

43. Natera has not made false and misleading statements disparaging AlloSure and CareDx by representing that AlloSure is of a lower standard, quality, or grade than it actually is and has not otherwise violated Section 8 of the DTPA.

44. Natera has not made false and misleading statements causing a likelihood of confusion or of misunderstanding as to the affiliation, connection, or association with Prospera® and AlloSure and has not otherwise violated section 12 of the DTPA.

45. Natera has not made false and misleading statements knowingly or recklessly.

46. Accordingly, Natera is entitled to a judgment declaring that it has not violated the DTPA, 6 Del. C. §§ 2532(a)(5), (8), (12).

COUNT FOUR
FALSE ADVERTISING UNDER THE LANHAM ACT
(15 U.S.C. § 1125(a))

47. Natera incorporates by reference all allegations set forth above as if fully set forth herein.

48. On information and belief, CareDx has made false and misleading statements, including but not limited to written promotional materials to healthcare professionals, insurance companies, patients, and others, about the performance and quality of its AlloSure product. CareDx has engaged in such acts in a manner that misleads healthcare professionals, insurance companies, patients, and others into believing that AlloSure's performance is better than it is, and that it is comparable to or more effective than Natera's Prospera® product.

49. On information and belief, CareDx markets and sells AlloSure in the United States and as such, CareDx's false and misleading statements were made in interstate commerce.

50. On information and belief, CareDx's false and misleading statements were made in the context of commercial advertising or promotion, as they were made for the purpose of influencing healthcare providers, insurance companies, patients, and others to use AlloSure.

51. On information and belief, CareDx's false and misleading statements were intended to deceive healthcare providers, insurance companies, patients, and

others about the performance and quality of AlloSure as comparable to or more effective than Natera's Prospera® product.

52. On information and belief, CareDx's false and misleading statements are material and will affect the purchasing and investment decisions of healthcare providers, insurance companies, patients, and others when choosing between CareDx's AlloSure product and Natera's Prospera® product.

53. CareDx's false and misleading statements have caused and are likely to cause substantial harm to Natera in the marketplace, including lost business and loss of goodwill and reputation.

54. Natera is entitled to injunctive relief, disgorgement of CareDx's ill-gotten profits, and recovery of damages in an amount to be ascertained through discovery and trial.

COUNT FIVE
TORTIOUS INTERFERENCE WITH PROSPECTIVE ECONOMIC ADVANTAGE

55. Natera incorporates by reference all allegations set forth above as if fully set forth herein.

56. Natera had a reasonable probability of a business opportunity with, among others, healthcare providers that would select Natera's Prospera® product for patients who have received a kidney transplant.

57. CareDx has intentionally interfered with that opportunity by, among other things, falsely and misleadingly suggesting that the data recounted in the UCSF Study is not reliable and/or that Prospera® is inferior to CareDx's AlloSure product.

58. CareDx has intentionally interfered with that opportunity by, among other things, falsely and misleadingly representing the facts of AlloSure's quality and performance.

59. CareDx's actions have proximately caused harm to Natera through the loss of said business opportunities.

60. CareDx's actions have caused Natera to be damaged in an amount to be ascertained through discovery and trial.

COUNT SIX
UNFAIR COMPETITION UNDER DELAWARE LAW

61. Natera incorporates by reference all allegations set forth above as if fully set forth herein.

62. Natera had a reasonable expectancy of entering into a valid business relationship with, among others, healthcare providers that would select Natera's Prospera® product for patients who have received a kidney transplant.

63. CareDx has wrongfully interfered with that reasonable expectancy by, among other things, falsely and misleadingly suggesting that the data recounted in

the UCSF Study is not reliable and/or that Prospera® is inferior to CareDx's AlloSure product.

64. CareDx has wrongfully interfered with that reasonable expectancy by, among other things, falsely and misleadingly representing the facts of AlloSure's quality and performance.

65. CareDx's wrongful actions defeated Natera's legitimate expectancy and caused harm in an amount to be ascertained through discovery and trial.

COUNT SEVEN
VIOLATION OF THE DELAWARE UNIFORM DECEPTIVE TRADE PRACTICES ACT

66. Natera incorporates by reference all allegations set forth above as if fully set forth herein.

67. CareDx has falsely represented that AlloSure has sponsorship, approval, characteristics, uses, benefits, or quantities that AlloSure does not have in violation of 6 Del. C. § 2532(a)(5).

68. CareDx has falsely represented that Prospera® is inferior to AlloSure because it is based on data that CareDx has falsely and misleadingly claimed to be unreliable in violation of 6 Del. C. § 2532(a)(7).

69. CareDx has disparaged Prospera® and Natera's business by false or misleading representation of fact relating to the quality of both Prospera® and the UCSF Study in violation of 6 Del. C. § 2532(a)(8).

70. CareDx has engaged in conduct that has created a likelihood of confusion and misunderstanding surrounding the quality of both Prospera® and the UCSF Study in violation of 6 Del. C. § 2532(a)(12).

71. CareDx has falsely represented that AlloSure's performance is better than it is, and that it is comparable to or more effective than Natera's Prospera® product in violation of 6 Del. C. § 2532(a)(7).

72. CareDx has disparaged Prospera® and Natera's business by false or misleading representation of fact relating to the quality of AlloSure in violation of 6 Del. C. § 2532(a)(8).

73. CareDx has engaged in conduct that has created a likelihood of confusion and misunderstanding surrounding the quality of AlloSure in violation of 6 Del. C. § 2532(a)(12).

JURY DEMAND

74. Natera requests a trial by jury on these counterclaims.

PRAYER FOR RELIEF

WHEREFORE, Natera respectfully requests that the Court enter an order awarding the following relief:

a. Judgment in favor of Natera and against CareDx;

b. An order preliminarily and permanently enjoining CareDx from disseminating or causing the dissemination of the false and misleading claims alleged herein;

c. An order requiring CareDx to take all necessary corrective measures to correct the false and misleading impressions created among healthcare professionals by the false and misleading claims alleged herein;

d. A declaration that Natera has not engaged in any false advertising, any unfair competition, and has not violated any section of the Delaware Uniform Deceptive Trade Practices Act;

e. Natera's actual monetary damages, including but not limited to Natera's lost business and profits, harm to Natera's goodwill and reputation, and CareDx's ill-gotten and unjustly derived revenues;

f. Punitive and exemplary damages;

g. Pre- and post-judgment interest on all money damages, as permitted by law;

h. Costs of this litigation, including expert witness fees, as permitted by law;

i. Attorneys' fees, as permitted by law;

j. Statutory damages, including multipliers and equitable enhancements, as permitted by law; and

k. Such other and further relief, at law or in equity, to which Natera is justly entitled.

MORRIS, NICHOLS, ARSHT & TUNNELL LLP

/s/ Jack B. Blumenfeld

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February 18, 2020

CERTIFICATE OF SERVICE

I hereby certify that on February 18, 2020, I caused the foregoing to be electronically filed with the Clerk of the Court using CM/ECF, which will send notification of such filing to all registered participants.

I further certify that I caused copies of the foregoing document to be served on February 18, 2020, upon the following in the manner indicated:

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